

WHAT IS CLAIMED IS:

- 1 1. A method for manufacture of autograft, allograft and xenograft implants which
2 comprises assembling such implants from smaller pieces of graft materials to
3 form a larger graft implant product.
- 1 2. A kit comprising assemblable parts of autograft, allograft and xenograft implants
2 for assembling such implants from smaller pieces of graft materials to form a
3 larger graft implant product which may be formed in the course of a surgical
4 procedure to precisely meet the needs of a given patient or procedure.
- 1 3. A method of strengthening or reinforcing autograft, allograft and xenograft
2 implants which comprises assembling such implants from smaller pieces of graft
3 materials to form a larger graft implant product.
- 1 4. The method of claim 3 wherein the reinforced product is cancellous bone into
2 which is inserted reinforcing material.
- 1 5. The method according to claim 4 wherein said reinforcing material comprises
2 cortical bone.
- 1 6. A graft implant comprising any one or combinations of allograft materials,
2 autograft materials, xenograft materials, synthetic materials, metallic materials
3 assembled into a an assembled implant which is assembled into a single graft by
4 use of reinforcing material to hold the constituent pieces of graft materials
5 together.
- 1 7. The graft implant according to claim 6 wherein said reinforcing material
2 comprises cortical bone.

1 8. The graft implant according to claim 6 wherein said any one or combinations of
2 allograft materials, autograft materials, xenograft materials, synthetic materials,
3 metallic materials are pretreated by a process comprising removing associated
4 non-bone adventitious materials from a bone graft to provide a cleaned bone graft,
5 contacting the cleaned bone graft with defatting solutions to provide a cleaned
6 defatted bone graft, and contacting said cleaned defatted bone graft with a
7 chaotropic agent to remove non-collagenous or non-structural collagen proteins.

1 9. The graft implant according to claim 8 wherein said chaotropic agent is selected
2 from urea, guanidinium hydrochloride, Tween, TritonX-100, TNBP, SDS, and
3 mixtures of these agents.

1 10. The graft implant according to claim 6 wherein said any one or combinations of
2 allograft materials, autograft materials, xenograft materials, synthetic materials,
3 metallic materials are pretreated by a process comprising cleaning, perfusion and
4 passivation process which comprises cyclic exposure of said implant to increased
5 and decreased positive or negative pressures, or both.

1 11. The graft implant according to claim 10 wherein a cleaning solution used during
2 the cleaning step is selected from the group consisting of: sterile water, Triton X-
3 100, TNBP, 3% hydrogen peroxide, a water-miscible alcohol, saline solution
4 povidone iodine, ascorbic acid solution, aromatic or aliphatic hydrocarbons,
5 ethers, ketones, amines, urea, guanidine hydrochloride, esters, glycoproteins,
6 proteins, saccharides, enzymes, gaseous acids or peroxides, and mixtures thereof.

1 12. The graft implant according to claim 6 wherein the assembled implant is pre-
2 treated or treated after assembly to incorporate biologically active or inert
3 materials.

1 13. An implant comprising segments of cortical bone, cancellous bone, cortical-
2 cancellous bone, or combinations thereof pinned to each other by means of

3 cortical bone pins, wherein, prior to assembly or after assembly, the graft
4 materials are soaked, infused, impregnated, coated or otherwise treated with bone
5 morphogenetic proteins (BMP's), antibiotics, growth factors, nucleic acids,
6 peptides, or combinations thereof.

1 14. The implant according to claim 6 comprising an assembled cancellous block, or
2 dowel, harvested from the iliac crest or another suitable site to form a Cloward
3 Dowel, iliac crest wedge, or cancellous bone block, dowel, reinforced by insertion
4 therein of cortical bone pins.

1 15. The implant according to claim 6 comprising a cortical bone implant reinforced
2 by insertion therein of at least one cortical bone pin.

1 16. The implant according to claim 6 comprising an assembled implant comprising
2 different segments of cortical bone, cancellous bone or both.

1 17. The implant according to claim 6 comprising an assembled implant comprising
2 different segments of cortical bone, cancellous bone, demineralized cortical or
3 cancellous bone, synthetic material, and combinations thereof.

1 18. The implant according to claim 17 wherein insertion of reinforcing pins provides
2 an implant with multiple load-bearing pillars.

1 19. The implant according to claim 18 wherein said pins protrude from the surface of
2 the implant to engage with inferior, superior or both surfaces of bone between
3 which the implant is inserted.

1 20. The implant according to claim 19 which is a spinal implant.

- 1 21. The implant according to claim 19 comprising a cancellous portion of bone
2 implant that has been compression molded, and then affixed to other portions of
3 cortical or cancellous bone machined according to different or similar principles.
- 1 22. The implant according to claim 6 in the form of a tapered dowel.
- 1 23. A method of repairing a bone implant which comprises insertion therein of at
2 least one cortical bone pin.
- 1 24. The method according to claim 23 which further comprises affixing a piece of
2 bone to an existing bone implant by affixing said piece of bone to said cortical
3 bone pin.
- 1 25. The method according to claim 1 for making an instrument for insertion of other
2 implants.
- 1 26. The method according to claim 24 which is an implant driver.
- 1 27. A method for salvaging an implant that does not meet manufacturing
2 specifications which comprises insertion of at least one cortical bone pin at a site
3 to reinforce said site such that in combination with said at least one cortical bone
4 pin, said implant meets manufacturing specifications.
- 1 28. An assembled implant comprising a first bone segment pinned to a second bone
2 segment with a flexible tissue affixed between said first bone segment and said
3 second bone segment
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- 5 29. The assembled implant according to claim 28 wherein said first and second bone
6 segments are affixed to each other by means of at least one cortical bone pin.
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- 1 30. An assembled graft implant comprising two or more individual segments fastened
2 together, said implant comprising at least one demineralized bone segment and at
3 least one mineralized bone segment.
- 1 31. The assembled graft implant of claim 30, wherein said at least one demineralized
2 bone segment comprises a region of mineralized bone.
- 1 32. The assembled graft implant of claim 30, wherein said demineralized or
2 mineralized segments are made from cortical bone, cancellous bone or both.
- 1 33. An assembled graft implant comprising two or more individual segments fastened
2 together, said implant comprising at least one synthetic segment and at least one
3 demineralized bone segment.
- 1 34. The assembled graft implant of claim 33, wherein said demineralized bone
2 segment comprises a region of mineralized bone.
- 1 35. The assembled graft implant of claim 33, wherein said synthetic segment is
2 comprised of stainless steel, titanium, cobalt chromium-molybdenum alloy, nylon,
3 polycarbonate, polypropylene, polyacetal, polyethylene oxide and its copolymers,
4 polyvinylpyrrolidone, polyacrylates, polyesters, polysulfone, polylactide, poly(L-
5 lactide) (PLLA), poly(D,L-lactide) (PLA), poly(glycolide) (PGA), poly(L-lactide-
6 co-D,L-Lactide) (PLLA/PLA), poly(L-lactide-co-glycolide) (PLA/PGA),
7 poly(glycolide-co-trimethylene carbonate) (PGA/PTMC), polydioxanone (PDS),
8 polycaprolactone (PCL), polyhydroxybutyrate (PHBT), poly(phosphazenes),
9 poly(D,L-lactide-co-caprolactone) (PLA/PCL), poly(glycolide-co-caprolactone)
10 (PGA/PCL), poly(phosphazene ester), polyanhydrides, polyvinyl alcohol,
11 hydrophilic polyurethanes, and a combination of one or more bioabsorbable
12 polymers.

- 1 36. The assembled graft implant of claim 33, wherein said at least one synthetic
2 segment comprises a first end and a second end, and wherein a demineralized
3 bone segment or a mineralized bone segment is attached to said first end or said
4 second end.
- 1 37. An assembled graft implant comprising two or more individual segments
2 fastened together, said implant comprising at least one synthetic segment and at
3 least one mineralized bone segment.
- 1 38. The assembled graft implant of claim 37, wherein said synthetic segment is
2 comprised of stainless steel, titanium, cobalt chromium-molybdenum alloy, and a
3 plastic of one or more members selected from the group consisting of nylon,
4 polycarbonate, polypropylene, polyacetal, polyethylene oxide and its copolymers,
5 polyvinylpyrrolidone, polyacrylates, polyesters, polysulfone, polylactide, poly(L-
6 lactide) (PLLA), poly(D,L-lactide) (PLA), poly(glycolide) (PGA), poly(L-lactide-
7 co-D,L-Lactide) (PLLA/PLA), poly(L-lactide-co-glycolide) (PLA/PGA),
8 poly(glycolide-co-trimethylene carbonate) (PGA/PTMC), polydioxanone (PDS),
9 polycaprolactone (PCL), polyhydroxybutyrate (PHBT), poly(phosphazenes),
10 poly(D,L-lactide-co-caprolactone) (PLA/PCL), poly(glycolide-co-caprolactone)
11 (PGA/PCL), poly(phosphazene ester), polyanhydrides, polyvinyl alcohol,
12 hydrophilic polyurethanes, and a combination of one or more bioabsorbable
13 polymers.
- 1 39. An assembled graft implant comprising two or more individual segments fastened
2 together, wherein said assembled graft comprises at least one segment comprised
3 of demineralized bone, mineralized bone, demineralized bone having a
4 mineralized region, or a synthetic material, and at least one other segment
5 fastened thereto that is comprised of demineralized bone, mineralized bone,
6 demineralized bone having a mineralized region, or a synthetic material.

1 40. A graft segment configured for assembly with at least one other segment, wherein
2 said graft segment comprises at least one mineralized bone region and at least one
3 demineralized bone region.

1 41. The graft segment of claim 40, wherein said mineralized bone region is attached
2 to or integrated with said demineralized bone region.

1 42. A graft segment according to claim 40, wherein said graft segment comprises a
2 central mineralized bone region and at least one demineralized bone region
3 integrated with said central mineralized bone region and positioned on one or
4 more sides of or surrounding said mineralized bone region.

1 43. A mixed composition segment configured for assembly with at least one other
2 segment, said mixed composition segment comprising a region comprised of
3 mineralized bone, demineralized bone or a synthetic material that is attached to or
4 integrated with another region comprised of mineralized bone, demineralized
5 bone or a synthetic material.

1 44. The mixed composition segment of claim 43, additionally assembled with at least
2 one other graft segment.

1 45. A method for manufacture of a mixed-composition segment for autograft,
2 allograft and xenograft graft implants comprising contacting a region of a
3 mineralized bone segment with a demineralizing solution for a period of time
4 sufficient to achieved a desired level of demineralization to said region.

1 46. The method of claim 45 further comprising removing a sufficient quantity of said
2 demineralizing solution from said first region to prevent a toxic or an
3 inflammatory response to said segment upon implantation into a patient in need
4 thereof.

- 1 47. The method of claim 46, wherein said contacting is repeated for at least one
2 additional region, and said removing step is done to said at least one additional
3 region at the same time or at a different time as for said first region.
- 1 48. A mixed-composition segment produced by the method of claim 45.
- 1 49. A mixed-composition segment produced by the method of claim 45, wherein at
2 least one region of said mixed-composition segment is mineralized bone, and at
3 least one region of said mixed-composition segment is demineralized bone.
- 1 50. A mixed-composition segment produced by the method of claim 45, wherein one
2 region of said mixed-composition segment is mineralized, and one or more
3 regions of said mixed-composition segment are demineralized, wherein said one
4 or more regions surround or sandwich said region of mineralized bone.
- 1 51. A method for manufacture of a mixed-composition segment for autograft,
2 allograft and xenograft graft implants comprising
3 a. contacting a first piece of graft material comprising bone with a
4 demineralizing solution for a period of time sufficient to achieve a desired
5 level of demineralization to said first piece; and
6 b. bonding or otherwise intimately attaching a portion (region) of said first
7 piece of demineralized graft material with a second piece of graft material,
8 said second piece of graft material being mineralized, demineralized, or
9 synthetic, such that said bonding or intimately attaching results in a single
10 integral mixed-composition segment; and
11 c. optionally, removing a sufficient quantity of said demineralizing solution
12 from said first region to prevent a toxic or an inflammatory response to
13 said segment upon implantation into a patient in need thereof.

- 1 52. The method of claim 51, wherein step (a) is repeated for at least one additional
2 piece, and step (b) is repeated to attach each at least one additional piece to form a
3 multi-piece (multi-region) mixed-composition segment.
- 1 53. A mixed-composition segment produced by the method of claim 51.
- 1 54. A mixed-composition segment produced by the method of claim 51, wherein at
2 least one region of said mixed-composition segment is mineralized bone, and at
3 least one region of said mixed-composition segment is demineralized bone.
- 1 55. A mixed-composition segment produced by the method of claim 51, wherein one
2 region of said mixed-composition segment is mineralized bone, and one or more
3 regions of said mixed-composition segment are demineralized bone, wherein said
4 demineralized bone regions surround or sandwich said region of mineralized
5 bone.
- 1 56. A kit comprising assemblable parts of autograft, allograft, xenograft and synthetic
2 segments for assembling mixed-composition implants from smaller pieces of graft
3 materials to form a larger graft implant product which may be formed in the
4 course of a surgical procedure to precisely meet the needs of a given patient or
5 procedure, and comprising at least one mixed-composition segment among said
6 assemblable parts.
- 1 57. A method of strengthening or reinforcing a mixed-composition segment for
2 autograft, allograft and xenograft graft implants which comprises assembling said
3 mixed-composition segment from smaller pieces of graft materials to form a
4 larger mixed-composition segment.
- 1 58. The method of claim 57 wherein said mixed-composition segment comprises
2 cancellous bone in combination with demineralized bone.

- 1 59. The method of claim 57 wherein the mixed-composition segment comprises
2 cortical bone in combination with demineralized bone.
- 1 60. An implant comprising segments of cortical bone, cancellous bone, cortical-
2 cancellous bone, or combinations thereof pinned to each other by means of
3 cortical bone pins, wherein, prior to assembly or after assembly, the graft
4 materials are soaked, infused, impregnated, coated or otherwise treated with bone
5 morphogenetic proteins (BMP's), antibiotics, growth factors, nucleic acids,
6 peptides, sodium hyaluronate, hyaluronic acid, polysulfated glycosaminoglycans,
7 or combinations thereof, and wherein, at least one of said segments is a mixed-
8 composition segment or demineralized bone.
- 1 61. An assembled implant comprising a first bone segment pinned to a second bone
2 segment, and comprising a flexible tissue affixed between said first bone segment
3 and said second bone segment, wherein said first bone segment is a mixed-
4 composition segment.
- 1 62. An assembled implant bone graft comprising at least two individual segments
2 joined together, and synthetic scaffolding material, wherein said synthetic
3 scaffolding material passes through and/or surrounds said segments, thereby
4 providing structural support to at least one of said at least two individual
5 segments.
- 1 63. An assembled bone graft comprising:
2 a. a first graft segment comprising at least one mineralized bone region, and
3 at least one demineralized bone region; and comprising at least one hole;
4 b. at least one other graft segment comprising at least one hole; and
5 c. at least one connector;
6 d. whereby the first graft segment and the at least one other graft segment are
7 joined physically by said at least one connector.

64. The bone graft of claim 63, wherein said first graft segment and said at least one other graft segment are joined physically by means of at least one pin, rod, bar, post or other linear connector passing through said at least one hole in said first graft segment which is arranged to align with said at least one hole of said other graft segment.

65. The bone graft of claim 63, additionally comprising a synthetic support structure that encompasses all or a part of said composite bone graft whereby the synthetic support structure bears load that would otherwise bear on at least one of said graft segments.

66. The bone graft of claim 65, wherein said synthetic support structure is comprised of a biocompatible material selected from the group consisting of stainless steel, titanium, cobalt chromium-molybdenum alloy, and a plastic of one or more members selected from the group consisting of nylon, polycarbonate, polypropylene, polyacetal, polyethylene oxide and its copolymers, polyvinylpyrrolidone, polyacrylates, polyesters, polysulfone, polylactide, poly(L-lactide) (PLLA), poly(D,L-lactide) (PLA), poly(glycolide) (PGA), poly(L-lactide-co-D,L-Lactide) (PLLA/PLA), poly(L-lactide-co-glycolide) (PLA/PGA), poly(glycolide-co-trimethylene carbonate) (PGA/PTMC), polydioxanone (PDS), polycaprolactone (PCL), polyhydroxybutyrate (PHBT), poly(phosphazenes), poly(D,L-lactide-co-caprolactone) (PLA/PCL), poly(glycolide-co-caprolactone) (PGA/PCL), poly(phosphate ester), polyanhydrides, polyvinyl alcohol, hydrophilic polyurethanes, and a combination of one or more bioabsorbable polymers.

67. A graft implant comprising any one or combinations of allograft materials, autograft materials, xenograft materials, synthetic materials, and metallic materials assembled into an assembled implant which is assembled into a single graft by use of reinforcing material to hold the constituent pieces of graft materials together, and comprising at least one mixed-composition segment.

- 1 68. The graft implant of claim 67 wherein said reinforcing material comprises cortical
2 bone.
- 1 69. The graft implant of claim 67 wherein the assembled implant is pre-treated or
2 treated after assembly to incorporate biologically active or inert materials.
- 1 70. The implant of claim 67 comprising an assembled cancellous block, or dowel,
2 harvested from the iliac crest or another suitable site to form a Cloward Dowel,
3 iliac crest wedge, or cancellous bone block, dowel, reinforced by insertion therein
4 of cortical bone pins.
- 1 71. The implant of claim 67 comprising a cortical bone implant reinforced by
2 insertion therein of at least one cortical bone pin.
- 1 72. The implant of claim 67 comprising an assembled implant comprising different
2 segments of cortical bone, cancellous bone or both.
- 1 73. The implant of claim 67 in the form of a tapered dowel.
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- 3 74. The implant of claim 67 comprising an assembled implant comprising different
4 segments of cortical bone, cancellous bone, demineralized cortical or cancellous
5 bone, or synthetic material, or combinations thereof.
- 1 75. The implant of claim 71 wherein insertion of reinforcing pins provides an implant
2 with multiple load-bearing pillars.
- 1 76. The implant of claim 75 wherein said pins protrude from the surface of the
2 implant to engage with inferior, superior or both surfaces of bone between which
3 the implant is inserted.
- 1 77. The implant of claim 67 which is a spinal implant.

- 1 78. The implant according to claim 67 comprising a cancellous portion of bone
2 implant that has been compression molded, and then affixed to other portions of
3 cortical or cancellous bone machined according to different or similar principles.
- 1 79. A bone implant comprising:
2 a. two or more bone segments,
3 b. at least one biocompatible connector,
4 c. wherein said at least one biocompatible connector fastens together said
5 two or more bone segments to form an assembled bone implant, said at
6 least one biocompatible connector does not comprise an adhesive.
- 1 80. The bone implant of claim 79, wherein at least one of said two or more bone
2 segments is a mixed composition segment.
- 1 81. An assembled bone graft comprising at least three segments, each said segment
2 comprising a first edge and a second edge at a side opposite from the first edge,
3 the first and second edges having interlocking structures mateable with an
4 adjacent edge of an adjacent segment, whereby each said segment's first and
5 second edges interlock with the edges of adjacent segments.
- 1 82. An assembled bone graft comprising at least three non-coplanar segments, each
2 said segment comprising a first mateable edge and a second mateable edge, each
3 of said mateable edges being mateable with an adjacent mateable edge of an
4 adjacent segment, whereby said assembled bone graft is assembled by mating said
5 first edges and said second edges of said segments positioned adjacent to one
6 another.
- 1 83. The assembled bone graft of claim 82, wherein said mateable edges interlock, and
2 are selected from the group of joint types consisting of ball and socket, tongue
3 and groove, and mortise and tenon.

- 1 84. The assembled bone graft of claim 82, additionally comprising at least one band
2 of flexible, non-stretchable material wrapped around the circumference of said
3 assembled bone graft.
- 1 85. The assembled bone graft of claim 82, wherein at least one of said segments is
2 comprised of a material selected from the group consisting of demineralized bone,
3 mineralized bone, a combination of demineralized and mineralized bone.
- 1 86. The assembled bone graft of claim 82, wherein at least one of said segments is
2 comprised of a material selected from the group consisting of cortical bone,
3 cancellous bone, and a combination of cortical and cancellous bone.
- 1 87. The assembled bone graft of claim 82, wherein at least one of said segments is
2 comprised of any one or combinations of allograft materials, autograft materials,
3 xenograft materials, synthetic materials, and metallic materials assembled into a
4 segment.
- 1 88. An assembled bone graft comprising a first and a second arcuate-shaped segment,
2 each segment comprising two interlocking edges, whereby each said edge of said
3 first segment interlocks with an edge of said second segment, forming an
4 assembled bone graft with an open channel between said first and second
5 segments.
- 1 89. A bone tendon bone-type graft useful in orthopedic surgery comprising at least
2 one block and a flexible band attached to said at least one block.
- 1 90. The bone tendon bone-type graft of claim 89, wherein at least one block of the at
2 least one block is comprised of a synthetic material, and the flexible band is
3 comprised of allograft or xenograft tendon, ligament, or processed dermis.

1 91. The bone tendon bone-type graft of claim 89, wherein at least one of the at least
2 one block is comprised of cortical bone, cancellous bone, cortico-cancellous bone,
3 or a combination of these, and the flexible band is comprised of a synthetic
4 material.

1 92. The bone tendon bone-type graft of claim 91, wherein said synthetic material is
2 comprised of a biocompatible material selected from the group consisting of
3 nylon, polycarbonate, polypropylene, polyacetal, polyethylene oxide and its
4 copolymers, polyvinylpyrrolidone, polyacrylates, polyesters, polysulfone,
5 polylactide, poly(L-lactide) (PLLA), poly(D,L-lactide) (PLA), poly(glycolide)
6 (PGA), poly(L-lactide-co-D,L-Lactide) (PLLA/PLA), poly(L-lactide-co-
7 glycolide) (PLA/PGA), poly(glycolide-co-trimethylene carbonate) (PGA/PTMC),
8 polydioxanone (PDS), polycaprolactone (PCL), polyhydroxybutyrate (PHBT),
9 poly(phosphazenes), poly(D,L-lactide-co-caprolactone) (PLA/PCL),
10 poly(glycolide-co-caprolactone) (PGA/PCL), poly(phosphase ester),
11 polyanhydrides, polyvinyl alcohol, and hydrophilic polyurethanes.

1 93. The bone tendon bone-type graft of claim 91, wherein at least one of the at least
2 one block is comprised of an assembled bone graft.

1 94. The bone tendon bone-type graft of claim 92, wherein the assembled bone graft is
2 comprised of at least one mixed-composition segment.

1 95. A method of assembling an assembled implant to obtain a desired interference fit,
2 comprising:

- 3 a. vacuum drying at least one bone pin to obtain a desired size reduction;
- 4 b. measuring the diameter of the at least one bone pin after vacuum drying;
- 5 c. making at least one hole in at least one bone piece to be assembled with
- 6 the at least one bone pin, wherein the hole is smaller than the diameter of
- 7 the at least one bone pin to obtain an interference fit;

- d. assembling the at least one bone pin with the at least one bone piece by inserting each of the at least one pin(s) through the at least one hole(s) to form the assembled implant; and
- e. freeze drying the assembled implant;
- whereby the interference fit(s) between the at least one bone pin and the at least one hole in the at least one bone piece fall within a desired range.

96. The method of claim 95 wherein the at least one bone pin is comprised of cortical bone, and optionally at least one of the at least one bone piece is comprised of cortical bone.

97. The method of claim 96 wherein the desired range for the interference fit is 0.001 to 0.003 inches.

98. The method of claim 96 wherein the vacuum drying is at room temperature, is conducted at a negative pressure of approximately 100 milliTorre, and lasts at least five hours.

99. An assembled implant comprising at least two substantially planar segments, wherein at least one of said at least two substantially planar segments comprise at least one slot defined thereon, and wherein said at least two substantially planar segments are fastened together by sliding said at least one slot of at least one planar segment over another substantially planar segment.

100. The assembled implant of claim 99, said implant comprising a first substantially planar segment and a second substantially planar segment, wherein said first and second substantially planar segments comprise a slot longitudinally defined thereon such that said first and second substantially planar segments comprise a slotted section and a body section, and wherein said first and second substantially planar segments are fastened together by sliding the slotted section of each over the body portion of the other.

1 101. A bone-tendon graft comprising at least one assembled bone block, wherein said
2 bone block is comprised of mineralized bone, demineralized bone or a synthetic
3 material, or a mixed composition; and at least one flexible band attached to said at
4 least one bone block, wherein said band is comprised of demineralized bone or of
5 a synthetic material.